DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

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Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6007

July 13, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Mr. Kenneth Friedberg
President
Bergen Institute of Medicine
316 Knickerbocker Road
Dumont, New Jersey 07628

FILE NO.: 00-NWJ-44
Inspection ID NO.: 1611660004

Dear Mr. Friedberg:

We are writing you because an inspection conducted by the State of New Jersey on behalf of the Food and Drug Administration (FDA) on June 2, 2000, revealed a serious regulatory problem involving mammography at your facility.

Under the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level One deficiencies:

- No documentation provided during time of inspection, which validated that the interpreting physician, [redacted] meets the requirement of being licensed by a State to practice medicine.

- No documentation provided during time of inspection, which validated that the interpreting physician, [redacted], meets the requirement of being licensed by a State to practice medicine.

- No documentation provided during time of inspection, which validated that the interpreting physician, [redacted], meets the requirement of being certified by an FDA-recognized board or having the alternative of 2 months training in the interpretation of mammograms.

This inspection also revealed the following Level Two deficiencies:

- The interpreting physician, [redacted] did not meet the continuing education requirement of having completed a minimum of 15 Continuing Medical Education (CME) credits in mammography in a 36-month period.
- The interpreting physician, [redacted] did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.
- The interpreting physician, [redacted] did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.
- The interpreting physician, [redacted] did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36-month period.
- The interpreting physician, [redacted] did not meet the initial experience requirement of having read or interpreted 240 patient examinations in a 6-month period.
- The interpreting physician, [redacted], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.
- The interpreting physician, [redacted], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.
- The interpreting physician, [redacted], did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36-month period.
- The interpreting physician, [redacted] did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.

- The interpreting physician, [redacted], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.

- Mammograms were processed in Processor One [redacted]) in the darkroom at this site when Processor One was out of limits on two days.

The specific deficiencies noted above appeared on your MQSA Facility Inspection Report that was issued to your facility at the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Mammography Quality Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction prohibiting your facility from conducting mammography services.

You must act on this matter immediately. Please explain or provide to this office in writing within 15 working days from the date that you receive this letter:

- the specific steps you have taken to correct the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: patient names or identification should be deleted from any copies submitted*).

*This note is not applicable for letters, which also address patient notification.

Please submit your response to Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings disclosed during the inspection of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have any specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Commander Heywood L. Rourk, Central Regional Radiological Health Representative, at (410) 962-4052.

Sincerely,

Edward H Wilkens, for
DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

cc: Bureau of Radiological Health
Department of Environmental Protection
Attn: Romona Chambus
P.O. Box 415
Trenton, New Jersey 08625-0415

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